UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,538	05/02/2005	Kei Kiribayashi	271390US0PCT	1631

22850 7590 11/18/2008

OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
HENRY, MICHAEL C	

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
11/18/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/533,538	KIRIBAYASHI ET AL.	
	Examiner	Art Unit	
	MICHAEL C. HENRY	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 11-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *18-20,31,32* is/are allowed.

6)☒ Claim(s) *1-5,11-17 and 21-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 08/01/08.

The amendment filed 08/01/08 affects the application, 10/533,538 as follows:

1. Claims 11-17 have been amended. New Claims 31-32 have been added. Applicant's amendments have overcome the rejection made under 35 U.S.C. 112, second paragraph and under 35 U.S.C. 101 of the prior office action mailed 04/21/08. Consequently, the said rejections are withdrawn. However, the rejections made under 35 U.S.C. 103(a) are maintained
2. The responsive to applicants' arguments is contained herein below

Claims 1-5 and 11-32 are pending in the application

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 11-17, 21-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isono et al. (US 5,871,477).

In claim 1, applicant claims a composition comprising adenosine triphosphate or a salt thereof, 1,000 to 4,000 mg/dL glucose, and electrolytes; wherein said composition is suitable for use as a peritoneal dialysate. Claims 2-5 are drawn to said composition which contains specific electrolytes, organic acid, lactic acid and which has specific osmotic pressure.

Isono et al. disclose a composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). In addition, Isono et al. disclose that organic acids such as lactic acid an citric acid can be used ((see col. 2, lines 5 to 46, especially lines 34-46).

The difference between applicant's composition and the composition of Isono et al. is that Isono et al.'s composition does not contain adenosine triphosphate. However, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46).

It would have been obvious to one having ordinary skill in the art at the time the claimed invention was made, in view of Isono et al., to prepare a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes in order to use it as a peritoneal dialysate.

One having ordinary skill in the art would have been motivated in view of Isono et al., to prepare a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes in order to use it as a peritoneal dialysate.

In claim 21, applicant claims a peritoneal dialysis method, comprising: administering into the peritoneal cavity of a subject in need thereof an effective amount of a composition comprising adenosine triphosphate or a salt thereof. Claims 22-30 are drawn to said method wherein said composition used contains specific electrolytes, organic acid, lactic acid and which has specific osmotic pressure, and wherein the subject has specific conditions.

Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). In addition, Isono et al. disclose that organic acids such as lactic acid an citric acid can be used (see col. 2, lines 5 to 46, especially lines 34-46). This suggests that said peritoneal composition disclosed by Isono et al. can be administered into the peritoneal cavity.

The difference between applicant's method and the method suggested by Isono et al. is that Isono et al.'s composition does not contain adenosine triphosphate. However, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate ((see col. 2, lines 5 to 46, especially lines 34-46)

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Isono et al., to administer a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of subject in need thereof.

One having ordinary skill in the art would have been motivated in view of Isono et al., to administer a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of a subject in need thereof. It should be noted that it is obvious to a skill artisan to prepare said peritoneal dialysate or composition with osmotic pressure or osmolarity that would physiological compatible when administered to said subject.

Claim 11 is drawn to a peritoneal dialysis method comprising: administering to a patient in need thereof a dialysate comprising adenosine triphosphate or a salt thereof. Claim 12 is drawn to the peritoneal dialysis method of claim 11, wherein said patient is suffering from a renal disease, and said dialysate is administered intraperitoneally via a catheter implanted in the peritoneal cavity. Claims 13-17 are drawn to said method wherein the adenosine triphosphate or a salt thereof is of specific concentration range, wherein the composition further comprises glucose, and an electrolyte, glucose of specific concentration range and further administering high level glucose.

Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). In addition, Isono et al. disclose that organic acids such as lactic acid an citric acid can be used (see col. 2, lines 5 to 46, especially lines 34-46). This suggests that said peritoneal composition disclosed by Isono et al. can be administered into the peritoneal cavity.

The difference between applicant's method and the method suggested by Isono et al. is that Isono et al.'s composition does not contain adenosine triphosphate. However, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate ((see col. 2, lines 5 to 46, especially lines 34-46).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Isono et al., to administer a composition comprising a

combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of subject in need thereof.

One having ordinary skill in the art would have been motivated in view of Isono et al., to administer a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate into the peritoneal cavity of a subject in need thereof. It should be noted that it is obvious to a skill artisan to prepare said peritoneal dialysate or composition with osmotic pressure or osmolarity that would physiological compatible when administered to said subject. It should be noted that the use of peritoneal dialysis to treat patients with renal disease is the extremely common in the art and is well within the purview of a skilled artisan.

Allowable Subject Matter

The following is an examiner's statement of reasons for allowance: The examiner has found claims 18-20, 31-32 to be unobvious over the prior art of record and therefore to be allowable over the prior art of record. The present invention relates a peritoneal dialysis method, characterized by employing a dialysate comprising adenosine triphosphate or a salt thereof in an effective amount. The very relevant prior art document (Isono et al. (US 5,871,477) to this invention discloses a composition comprising adenosine triphosphate, glucose and electrolytes and but does not disclose nor suggest the use of said composition in a peritoneal dialysis method as claimed in the instant invention.

Response to Arguments

Applicant's arguments with respect to claim 1 have been considered but are not found convincing.

The applicant argues that there is no suggestion in Isono to add adenosine triphosphate to a dialysate such as that described in col. 2, lines 10-17. Rather, col. 2, lines 35-47 of Isono specifically refer to modify organ preserving solutions like the glucose-free Eurocollin's solution described in col. 2, lines 26-34 with a variety of proposed additives. However, as set forth in the rejection above, Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). In addition, Isono et al. disclose that organic acids such as lactic acid an citric acid can be used (see col. 2, lines 5 to 46, especially lines 34-46). This suggests that said peritoneal composition disclosed by Isono et al. can be administered into the peritoneal cavity (see rejection above).

The applicant argues that Isono does not suggest the specific combination of glucose and adenosine triphosphate, nor suggest incorporating 1-4 g/dl of glucose into an organ preserving solution, and provides no suggest at all to incorporate both of these ingredients into a dialysate. However, as set forth in the rejection above, Isono et al. disclose a peritoneal dialysate composition comprising 1 to 8 g/dL glucose (i.e., 1,000- 8000 mg/dL) and electrolytes; wherein said composition can be used a peritoneal dialysate (see col. 2, lines 5 to 46). Furthermore, Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preservation solution can be added to said peritoneal dialysate (see col. 2, lines 5 to 46, especially lines 34-46). In addition, Isono et al. disclose that organic acids such as lactic acid an citric acid can be used (see col. 2, lines 5 to 46, especially lines 34-46). This suggests that said

peritoneal composition disclosed by Isono et al. can be administered into the peritoneal cavity (see rejection above). It should be noted that the use of peritoneal dialysis to treat patients with renal disease is the extremely common in the art and is well within the purview of a skilled artisan.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry
November 9, 2008.

/Shaojia Anna Jiang/
Supervisory Patent Examiner
Art Unit 1623